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IN THE U[illegible]ED STATES PATENT AND TRADEMAR[illegible]FFICE

In re Patent Application of

MAERTENS, et al.

Serial No. 09/851,138

Filed:

Atty Dkt. 2551-106
C# M#

Group Art Unit: 1648

Examiner: Li

Date: April 11, 2003

OIPE JC99 APR 11 2003 PATENT & TRADEMARK OFFICE

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Title: SEQUENCES OF HEPATITIS C VIRUS GENOTYPES AND THEIR USE AS PROPHYLACTIC, THERAPEUTIC AND DIAGNOSTIC AGENTS

Assistant Commissioner for Patents
Washington, DC 20231

Sir:

RESPONSE/AMENDMENT/LETTER

This is a response/amendment/letter in the above-identified application and includes an attachment which is hereby incorporated by reference and the signature below serves as the signature to the attachment in the absence of any other signature thereon.

☐ **Correspondence Address Indication Form Attached.**

Fees are attached as calculated below:

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Total effective claims after amendment **0** minus highest number previously paid for **20** (at least 20) = 0 x $ 18.00	$	0.00
Independent claims after amendment **0** minus highest number previously paid for **3** (at least 3) = 0 x $ 84.00	$	0.00
If proper multiple dependent claims now added for first time, add $280.00 (ignore improper)	$	0.00
Petition is hereby made to extend the current due date so as to cover the filing date of this paper and attachment(s) ($110.00/1 month; $410.00/2 months; $930.00/3 months)	$	0.00
Terminal disclaimer enclosed, add $ 110.00	$	0.00
☐ First/second submission after Final Rejection pursuant to 37 CFR 1.129(a) ($750.00) ☐ Please enter the previously unentered , filed ☐ Submission attached	$	0.00
Subtotal	$	**0.00**
If "small entity," then enter half (1/2) of subtotal and subtract ☐ Applicant claims "small entity" status. ☐ Statement filed herewith	-$	0.00
Rule 56 Information Disclosure Statement Filing Fee ($180.00)	$	0.00
Assignment Recording Fee ($40.00)	$	0.00
Other: Amendment; Rule 181 Petition; Copy of U.S. Patent 6,180,768 (pg. 1 and columns 175-178; Copy of Petition Decision (3/19/03); Submission of Drawings (74 sheets); Rule 181 Petition Fee		**130.00**
TOTAL FEE ENCLOSED	$	**130.00**

The Commissioner is hereby authorized to charge any deficiency, or credit any overpayment, in the fee(s) filed, or asserted to be filed, or which should have been filed herewith (or with any paper hereafter filed in this application by this firm) to our Account No. 14-1140. A duplicate copy of this sheet is attached.

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NIXON & VANDERHYE P.C.
By Atty: B. J. Sadoff, Reg. No. 36,663

Signature: [signature]

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PATENT & TRADEMARK OFFICE

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of

Maertens et al Atty. Ref.: **2551-106**

Serial No. **09/851,138** Group: **1648**

Filed: **May 9, 2001** Examiner: **Li**

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For: **NEW SEQUENCES OF HEPATITIS C VIRUS GENOTYPES AND THEIR USE AS PROPHYLACTIC, THERAPEUTIC AND DIAGNOSTIC AGENTS**

* * * * * * * * * * * *

April 11, 2003

Assistant Commissioner for Patents
Washington, DC 20231

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Sir:

RULE 181 PETITION

The Commissioner is requested to invoke his supervisory authority and have the restriction requirement of September 20, 2002 (Paper No. 8), withdrawn and instruct the Examiner to allow the pending claims. Consideration of the following in this regard is requested.

A Response to the Office Action of September 20, 2002, has been filed on December 20, 2002. The Examiner has presumably made the restriction requirement final. See, pages 1 and 2 of Paper No. 11.

The present Rule 181 Petition is being filed to expedite prosecution and consideration of the restriction requirement by the Commissioner prior to the Examiner's issuance of a further Office Action on the merits.

The Commissioner is urged to appreciate that the subject matter of the present claims has been allowed and issued as U.S. Patent No. 6,180,768, which was

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withdrawn, at the applicants request, as evidenced by the Notice published at 1243 OG 1040, February 27, 2001 (copy attached). The attached marked-up copy of the claims of U.S. Patent No. 6,180,768 indicates by underlining the subject matter of the previously allowed claims which is currently claimed. As indicated in the attached, the Patent Office has already examined and allowed the presently claimed subject matter, in a single application, and further examination of the presently claimed invention should not place an undue burden on the Examiner, or even require further extensive search. For completeness, the applicants note that SEQ ID NOs:138, 155, 174, 190 and 207 of claim 65 are unique to SEQ ID NO:52 and the HCV type 10 isolate such that these sequences are included is allowed claim 4 subpart (ii) of U.S. Patent No. 6,180,768.

The Commissioner is requested to invoke his supervisory authority and have the restriction requirement of September 20, 2002, withdrawn and the claims allowed.

The restriction requirement should further be withdrawn for any of the following reasons.

The Examiner has apparently "rejoined" claim 68 with the elected Group I of Paper No. 8 (see, page 2, paragraph 1 of Paper No. 11) while excluding claim 67 (see, page 2, paragraph 2 of Paper No. 11) for unknown or at least unclear reasons ("in consistent with the Patent Office's previous treatment" Id.). The Examiner appears to have misunderstood the applicants' previous arguments and withdrawn claim 67 from the elected Group. As noted previously, although the method of claim 67 is grouped together with the subject matter of the HCV polynucleic acids, the product of the method and amino acid sequences encoded by the nucleic are not. This is contrary to the

Patent Office's previous treatment of this subject matter, as evidenced by the allowed claims of U.S. Patent No. 6,180,768. The applicants submit that the structure of the polypeptides of the invention is dictated by the structure of the polynucleic acids, as believed to be recognized by the Examiner in her grouping of the subject matter of claim 67 together with the subject matter of any of claims 63, 64 or 65.

The Commissioner will appreciate that claim 63 is directed, in part, to a nucleic acid sequence having the sequences of SEQ ID NO:51. SEQ ID NO:51 is a nucleic acid sequence. SEQ ID NO:52 is an amino acid sequence encoded by the nucleic acid sequence of SEQ ID NO:51. Accordingly, the subject matter of claim 65, as it relates to SEQ ID NO:52, is defined by SEQ ID NO:51, as recited in claim 63. The Examiner however has asserted that the subject matter of claims 63 and 65 are patentably distinct. See, Groups I and III on page 2 of Paper No. 8.

Moreover, the Commissioner will appreciate that the recitations of SEQ ID NOs: 138, 155, 174, 190 and 207 are directed to segments of the amino acid sequence of SEQ ID NO:52, also recited in claim 65. Specifically, SEQ ID NO:138 is amino acids 33-48 of SEQ ID NO.52; SEQ ID NO:155 is residues 54-64 of SEQ ID NO:52; SEQ ID NO:174 is residues 71-83 of SEQ ID NO:52; SEQ ID NO:190 is residues 89-98 of SEQ ID NO:52; and SEQ ID NO:207 is residues 135-144 of SEQ ID NO:52. A search of claim 63 which includes the nucleotide sequence of SEQ ID NO:51 would appear to require a search of the subject matter of claim 65, i.e., a nucleotide sequence encoding, for example, SEQ ID NO:52. Accordingly, the claimed "inventions" are not "unrelated", as asserted by the Examiner at page 2 of Paper No. 8.

SEQ ID NO:52 is an amino acid sequence encoded by the nucleotide sequence of SEQ ID NO:51. A search of the subject matter of the Examiner's Groups I and III therefore are believed to be coextensive.

The applicants appreciate the Examiner's comment in paragraph 3 on page 2 of the Office Action of September 20, 2002 (Paper No. 8), noting the typographical error in claim 65 wherein SEQ ID NO:50 was referred to as opposed to the corrected SEQ ID NO:52. The Examiner's basis therefore for the restriction requirement stated in paragraph 3 of Paper No. 8 is moot in view of the previous amendments.

More importantly, the Examiner only indicates a basis for requiring restriction between the subject matter of Groups I and III in paragraph 3 of Paper No. 8 and fails to support the requirement for a restriction requirement between the subject matter of the other identified Groups.

Reconsideration and withdrawal of the restriction requirement therefore are requested.

The applicants again note however that the restriction requirement is further improper due to the fact that the subject matter of claims 63 and 65, as well as all the pending claims, has been allowed in the parent application, without requiring restriction between the separate claims. See, the attached copy of the claims of U.S. Patent No. 6,180,768, wherein SEQ ID NO:51 of the pending claim 63 is recited in the allowed claim 2; the amino acid residues recited in the pending claim 64 are recited in the allowed claim 3 and SEQ ID NO:52 of the pending claim 65 is recited in the allowed claim 4. Moreover, the subject matter of the pending claims 66-70 are believed to be

found in the previously allowed claims 7-11 of U.S. Patent No. 6,180,768. Accordingly, the pending claims are submitted to be allowable and, as the subject matter has been previously examined by the Patent Office in one application, the restriction requirement of September 20, 2002, should be withdrawn.

As noted above, the Examiner has not provided a sufficient basis in, for example, paragraph 3 of Paper No. 8, or in Paper No. 11 as to how each of the separate Groups of subject matter are patentably distinct one from the other.

The Examiner has classified essentially the same nucleic acid sequence in each of classes 424, subclass 186.1; class 424, subclass 228.1 and class 536, subclass 23.1. See, page 2 of Paper No. 8. Even if the Examiner's classification is correct, the applicants submit that the search of two subclasses within class 424 (i.e., subclasses 186.1 and 228.1) should not create an undue burden on the Examiner. More importantly, the applicants believe that class 424 relates to "drug, bio affecting and body treating compositions" while class 536 is believed to relate to "organic compounds". The applicants believe this separate classification is inappropriate and should be withdrawn as a basis for the restriction requirement, especially in view of the claims of the parent U.S. Patent No. 6,180,768, wherein the Patent Office has already conducted a search of all the claimed subject matter in class 435, subclasses 5, 7.1 and 320.1; class 435, subclasses 69.3 and 252.3; class 530, subclasses 300, and 350; and class 536, subclasses 23.1, 23.7 and 24.3, assuming the undersigned has correctly interpreted the attached first page of U.S. Patent No. 6,180,768.

The Commissioner is further urged to appreciate that although written in independent form, the HCV polynucleic acid molecules of claim 64(i) describes sequences of SEQ ID NO:51, such as recited in claim 63, which includes sequences also of claim 65. Accordingly, the subject matter of claims 63, 64 and 65, which is the basis for the Examiner's restriction requirement of separate Groups I to III, is believed to define a single invention and withdrawal of the restriction requirement is requested.

The restriction requirement should be withdrawn, all the claims should be examined together and a Notice of Allowance should be issued as the claimed subject matter has been previously allowed in U.S. Patent No. 6,180,768.

The requisite Petition fee is attached.

Respectfully submitted,

NIXON & VANDERHYE P.C.

By: _____

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